Docket No.: V9661.0069
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: Joseph Peiris et al.	Confirmation No.:2460
Application No.: 10/808,121	Art Unit: 1632
Filed: March 24, 2004	Examiner: Not Yet Assigned
For: A NOVEL HUMAN VIRUS CAUSING SEVERE ACUTE RESPIRATORY SYNDROME (SARS) AND USES THEREOF	New York, NY September 15, 2004

PETITION TO MAKE SPECIAL UNDER 37 C.F.R. § 1.102(d)

MAIL STOP PETITION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a Petition to Make Special the above-identified patent application.

I. Petition

Applicants hereby petition to make the above-identified application special under MPEP § 708.02 VIII. The application has not yet been examined.

II. Claims

All the claims in this case are directed to a single invention. If the Office determines that all the claims presented are not directed to a single invention,

applicants will make an election without traverse in fulfillment of this prerequisite to the granting of special status.

III. Search

Pre-examination searches were conducted by Science IPSM (The CAS Search Service; 2540 Olentangy River Rd., Columbus, OH 43202) as shown below. Copies of the search results are attached hereto. The references uncovered and deemed most relevant to the subject matter encompassed by the claims are listed below and on the attached Form PTO-1449.

(i) Sequence searches were conducted on July 14, 2004. For SEQ ID NOS:1, 3, 11, and 13 (DNA sequences) and SEQ ID NOS:2, 4 and 12 (amino acid sequences), BLAST similarity searches were conducted in DGENE, REGISTRY, and PCTGEN databases. Sequences with 90-100% similarity to the query sequences were selected. For SEQ ID NO:15 (DNA sequence), a BLAST similarity search was conducted in the CAS's REGISTRY database only. Sequences with 90-100% similarity to the query sequences were selected. The results were limited to documents prior to April 23, 2003, which is the latest filing date of the provisional applications whose benefits the present application claims. For non-patent documents, the results were limited to those prior to 2004.

(ii) Keyword searches were conducted on July 19, 2004, in the medicine, bioscience and patent-full text files found on the STN International online system (comprising more than 70 databases) using the terms below. The results were limited to documents prior to April 23, 2003. For non-patent documents, the results were limited to those prior to 2004.

-- Coronaviridae or Coronavirus or Coronaviruses or corna(w)(virus or viruses); and

-- (respiratory or gastroenter?)(s)(virus or viruses or viral); and

-- atypical(a)pneumonia#; but NOT

--atypical(a)pneumonia#(s)(mycoplasma? or chlamidia?).

(iii) Patent classification codes listed below were searched in combination with the keywords listed above in patent databases: USPATFULL, USPAT2, IFIPAT, JAPIO, PCTFULL, EUROPSTFULL, WPINDEX, and HCAPLUS. The results were limited to publication or application or priority dates prior to April 23, 2003.

U.S. patent class/subclass classifications

530/300, 350 and 826;

435/5, 91.1, 91.32, 235.1, 239, 69.3, 69.1 and 252.3;

536/23.1, 23.7, 23.72, 24.3, 24.32 and 24.33;

514/2, 8 and 44; and

424/185.1, 186.1, 204.1, 221.1 and 223.1.

International patent classifications

A61K 38/00, 39/00, 39/12 abd 39/215; and

C07K 14/00 and 14/165.

IV. Copies of References

A copy of each reference listed on the PTO-1449 is attached hereto.

V. Discussion of References

A. Publications before April 23, 2003

(BA)[1] *ASIAN J.MOD.MED.*, (1974) 10(11):412-416.

[1] Cite No. in the PTO-1449 form.

This article discusses "viral pneumonia" from a contemporary expert's view.

(BB) *Virus Research*, (April, 1999) 60(2):181-189.

This article discloses a consensus PCR assay to identify as yet unknown coronaviruses using degenerate primers based on a 251-bp subregion of a highly conserved 922 nucleotide region in open reading frame (ORF) 1b of the polymerase (*pol*) gene of eight conronaviruses. This protocol was able to detect four (4) group-1 viruses (229E, FIPV, TGEV, CCV), five (5) group-2 viruses (OC43, BCV, MHV, SDAV, HEV), one (1) group 3-virus (IBV), and TCV (previously placed in group 2). Also presented is a phylogenetic analysis of coronaviruses based on the 922-bp region.

(BC) *SENDROM*, (1 Apr 2003) 15(4):88-95.

According to the English Summary section of the article, it reports the clinical course and chest radiographic findings of a case of SARS with fatal outcome and the general status of SARS epidemic at that time.

B. Publications sometime in 2003

(BD) Problemy Osobo Opasnykh Infektsii, (2003) 85:164-170.

The English abstract at the end of the article describes as follows:

Algorithm of SARS laboratory diagnostics based on WHO recommendations is considered. Variant of test-system for SARS-CoV RNA detection using PCR, developed in Russian Anti-Plague Research Institute "Microbe", is described.

C. Publications on and after April 23, 2003

The publications on or after April 23, 2003 are also submitted herewith for examiner's reference. None of these references are deemed to be prior art to the present invention.

(BE) *Lancet*, (May 24, 2003) 361(9371):1779-1785

This article provides the entire genome sequences of Singapore isolates of SARS viruses and compare them with the isolates from Canada, Hong Kong, Hanoi, Guangzhou and Beijing.

(BF) *Science*, (May 30, 2003) 300(5624):1399-1404.

The article provides the genomic sequence of the TOR2 isolate from Canada and compares it with three previously known groups of coronaviruses phylogenetically.

(BG) Science, (May 30, 2003) 300(5624):1394-1399.

The article discloses the entire genome as well as the gene organization of SARS-CoV (Urbani strain) and compare it with known coronaviruses and phylogenetically analyzes the relation of SARS-CoV with other coronaviruses.

(BH) *Chinese Science Bulletin*, (May, 2003) 48(10):941-948.

The article provides the entire genome sequence of SARS-associated virus (Isolate BJ01) , GC distribution and phylogenetic analysis. The result indicated that there were putative 30 substitutions, of which 15 lead to possible amino acid changes in the proteins, indicating. Further, three of the substitutions were found in the S protein, indicating a possible immunoreactions between the virus and its host. These results suggested a possibility that SARS-associated viruses may have a non-human origin.

(BI) *Journal of Peking University, Health Sciences*, (May 31, 2003) 35 Suppl:70-71.

The article discloses the analysis of S protein of SARS virus using the methods of immunoinformatics and found that S protein epitopes were strikingly changed or even disappeared in SARS virus, unlike other common human coronaviruses.

(BJ) *Journal of General Virology*, (June, 2003) 84(9):2305-2315.

This article discloses the genomic sequence of SARS virus (Frankfurt 1 strain) and characterizes gene expression in terms of subgenomic mRNAs and translation of key replicative proteins by frame-shifting and post-translational processing.

(BK) *Chinese Science Bulletin,* (June, 2003) 48(12):1165-1169.

The article discloses a design and application of an oligo-microarray assay using 60mer oligonucleotides that are constructed based on the sequence of SARS virus TRO2 strain.

(BL) *Zhongguo Mianyixue Zazhi,* (June, 2003) 19(6):372-374.

The article provides the time course of SARS-specific IgM and IgG responses in twenty (20) patients in SARS and suggests the IgG's role in developing protective immunity.

(BM) *Chinese Journal of Virology,* (June, 2003) 19(2):97-99.

This article reports that partial sequences of RNA polymerase gene from two (2) dead SARS patients' lung and spleen samples were obtained using nested RT-PCR. The amplified PCR products had the same sequence as those of other SARS viruses found at different geographical locations.

(BN) *Genomics, Proteomics & Bioinformatics,* (August, 2003) 1(3):180-192.

This article discloses the complete genome sequences of the BJ Group and, based on the haplotypes and other sequence variations of SARS-CoV isolates from Canada, U.S.A., Singapore, and China, indicates the phylogenetic relations among the different isolates.

(BO) *Biopolimery I Kletka,* (September, 2003) 19(5):414-431.

According to the English Summary section of the article, the article discusses general characteristics of SARS-CoV and virion structure, thirty-six (36) complete sequences of different SARS-CoV and phylogenetic analysis. Potential S-protein binding sites with a putative receptor-aminopeptidase hAPN are predicted by bioinformatics and structural method. Also, it considers Mpro proteinase and its active site organization to designing potential SARS-CoV inhibitors.

(AA) U.S. Patent Application Publication No. US2003/0224353 (Application no. 10/422,671 filed April 24, 2003) published December 4, 2003.

This application is a continuation-in-part of application no. 10/272,865 filed October 2002, claiming the benefit of the provisional application no. 60/329,815 filed October 16, 2001. This patent application publication discloses antiviral compounds and methods of their use in inhibition of growth of viruses, among others, coronavirus, such as SARS virus. This publication was detected due to the 99% sequence identity of the 641-bp of AY274119 with SEQ ID NO:1 of the present application.

(BP) *Chinese Journal of Pediatrics*, (September, 2003) 41(9) 641-4.

This article discloses a detection of a 17-year old female patient with confirmed SARS infection by a RT-PCR method using the primers based on common respiratory viruses and the primer sequences published online by WHO on April 18, 2003.

(BQ) *Lancet*, (November 29, 2003) 362:1807-08.

This article discloses two different genomic sequences of SARS virus isolated from five Amoy Gardens patients. Either sequence has 99% identity with the sequence disclosed in the present application.

VI. Fee

Pursuant to 37 C.F.R. § 1.102(d), a fee of $130.00 is due for this petition, payment of which is being made by credit card. Form PTO-2038 is attached hereto. The Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. 50-2215, under Order No. V9661.0069. A duplicate copy of this paper is enclosed.

Accordingly, applicants request that this Petition to Make Special be granted and the application undergo accelerated examination.

Dated: September 15, 2004

Respectfully submitted,

By _____

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Attachments:

Search results based on:

1. Keywords;
2. U.S. and International Patent Classification;
3. SEQ ID NOS: 1, 2, 3, 4, 11, 12, 13, 14 and 15;

Copies of references